

REMARKS

In response to the Office Action dated November 9, 2010, Applicants have amended claims 1-16 and 38. No claims have been canceled and no new claims have been added. It is urged that support for all of the above amendments may be found throughout the as-filed specification and original claims, for example, on page 7, lines 14-24; page 12, lines 6-12; and Figures 1, 3, and 7-9. No new matter has been added. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 1-16 and 37-38 are pending and under examination. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

CLAIM OBJECTIONS

Claims 1-16 and 37-38 are objected to because of informalities.

Claims 1-3, 7-10, and 12 are objected to because they refer to the reactor vessel as reference numbers 26 and 61. Specifically, the Examiner alleges that it would be simpler to refer to just one reference number. Applicants respectfully agree. Applicants respectfully submit that one having ordinary skill in the art would understand and appreciate from the as-filed specification and associated drawings that both reference numbers 26 and 61 refer to the reactor vessel. Applicants have amended the claims to recite reference number 26, which relates to both reference numbers 26 and 61 in the specification and drawings as filed. Thus, Applicants respectfully submit that this basis of objection has been obviated and may be properly withdrawn.

Claim 1 is further objected to because the term "the" prior to "controlled conditions" in the second line of step (b) of claim 1, should be deleted. Applicants have deleted the term "the" as suggested by the Examiner; thus obviating this basis of objection.

Claim 3 is further objected to because the recitation "biological component" in the third line of step (a) should be replaced with "biological components." Applicants have amended

the first instance of “biological components” in the preamble to recite “biological component”; thus obviating this basis of objection.

Claims 2 and 4-16 are objected to because the term “A” at the beginning of each of these claims should be replaced with “The.” Applicants thank the Examiner for noting this error. Applicants have amended claims 2 and 4-16 to recite “The”; thus obviating this basis of objection.

Claim 38 is objected to as the recitation “*Escherichia coli* H7:O157” is the improper name for the strain known as “*Escherichia coli* O157:H7.” Applicants have amended the term “*Escherichia coli* H7:O157” to recite “*Escherichia coli* O157” thus obviating this basis of objection. Applicants submit that support for this amendment can be found throughout the specification as filed, for example, on page 20, line 29; thus, no new matter has been added by way of this amendment.

Applicants respectfully request reconsideration and withdrawal of these bases for objection.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-16 and 37-38 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential elements, such omission amounting to a gap between the elements. Specifically, the Examiner alleges the omitted elements are magnetic microparticles. Applicants respectfully traverse this basis for rejection.

Applicants, without acquiescence, have amended claim 1 and 3 to recite wherein the microparticles are magnetic particles, thus obviating this basis of rejection. Applicants submit that support for this amendment can be found throughout the specification as filed, for example, on page 1, lines 26-27; thus, no new matter has been added by way of this amendment.

Claims 1-16 and 37-38 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse each basis for this rejection.

The Examiner alleges that claim 1 is indefinite because claim 1, step (b) requires microparticles to bind to the biological component in the solution, but it is not clear that there are biological components in the solution. Applicants, without acquiescence, have amended claim 1 to more clearly recite that there are biological components in the solution; thus obviating this basis for rejection.

The Examiner further alleges that claim 1 is indefinite because there is insufficient antecedent basis for the limitation “the controlled conditions” in the fifth line of the claim. Applicants have deleted the term “the”; thus obviating this basis of rejection.

The Examiner alleges that claim 3 is indefinite because the definition of the term “magnetic synthesis” is unclear and because it is unclear from the term “biological component to be synthesized” how the synthesis takes place and whether the synthesis has already occurred. Applicants, without acquiescence, have deleted the terms “synthesis” and “synthesized”; thus obviating these bases of rejection.

The Examiner also alleges that claim 3 is indefinite because it is unclear from the term “proper activity and/or binding properties” what activity and binding activities would be deemed proper or for which purposes are they proper. Applicants, without acquiescence, have amended the term “proper activity and/or binding properties” to recite “an enzymatic activity and/or binding properties.” Applicants submit that support for this amendment can be found throughout the specification as filed, for example, from page 18, line 32 to page 20, line 7. Thus, no new matter has been added by way of this amendment. Applicants respectfully submit that the skilled artisan would readily appreciate that the enzymatic activity or binding property could be selected depending on the particular application using no more than routine knowledge in the art of molecular biology.

The Examiner additionally alleges that claim 3 is indefinite because it is unclear from the term “if needed” whether the mixing step is a required limitation and what is judged to determine the need for mixing. Applicants, without acquiescence, have deleted the term “if needed”; thus obviating this basis of rejection.

The Examiner also alleges that claim 3 is indefinite because it is unclear from the term “desired reaction and/or binding reaction” how the reactions relate to the synthesis, binding, isolation, purification, enrichment of the biological components and what characteristics would be required to deem a reaction desired. Applicants, without acquiescence, have amended the term “desired reaction and/or binding reaction” to recite “desired enzymatic reaction and/or binding reaction.” Applicants respectfully submit that the skilled artisan would readily appreciate that a desired enzymatic reaction or binding reaction would depend on the particular application. In one non-limiting example, if the desire were to purify ligated nucleic acids, a solution comprising one or more nucleic acid sequences could be contacted with a microparticle conjugated to ligase; thus, enriching for ligated nucleic acids. In another example, if the desire were to isolate a particular nucleic acid sequence, a solution comprising one or a plurality of nucleic acids could be contacted with a microparticle conjugated to the complement of the desired nucleic acid sequence; thus resulting in the binding of the desired sequence to the microparticle. Accordingly, the skilled artisan would recognize what constitutes the desired enzymatic reactions or binding reactions, depending on the particular application.

Finally, the Examiner alleges that claim 3 is indefinite because it is unclear if any synthesis, binding, isolation, purification, or enrichment of biological components occurs and because it is unclear how the microparticles relate to the biological component recited in step (a). Applicants have amended claim 3 to recite that the biological components bind to microparticles; thus obviating this basis of rejection.

The Examiner alleges that claims 4, 7, and 8 are indefinite because the term “the closed reactor unit (60)” lacks antecedent basis. Applicants have amended the term “the closed reactor unit (60)” to recite “a closed reactor unit (60)”; thus obviating this basis of rejection.

The Examiner alleges that claim 7 is indefinite because the claim does not recite that the biological components were ever bound to the microparticles and thus, lacks antecedent basis for the term “biological particles bound to microparticles.” Applicants have amended claim 3 to recite that the biological components bind to microparticles; thus obviating this basis of rejection.

Claims 13-16

The Examiner alleges that claims 13-16 are indefinite because it is unclear how these claims relate to the enrichment of the desired biological component of claim 1, or to the synthesis, binding, isolation, purification, or enrichment of the biological components of claim 3. Applicants respectfully submit that claim 13 recites different components bound to the microparticles, which the skilled artisan would understand allows different biological components to be bound, isolated, purified, or enriched by the microparticles.

Applicants respectfully submit that claim 14 recites using the microparticles to carryout chromatographic purification of the biological components, which the skilled artisan would understand is one way of further isolating, purifying, or enriching biological components bound to the microparticles.

Applicants respectfully submit that claim 15 recites isolating or enriching biological components that are pathological bacteria, viruses, parasites, or protozoans. Applicants respectfully submit the claim 15 is clearly directed to a subset of biological components of claims 1 and 3.

Similarly, Applicants respectfully submit that claim 16 is clearly directed to purifying a subset of biological components of claims 1 and 3, namely DNA, RNA, mRNA, proteins, peptides, cells, or cell organelles.

Accordingly, Applicants respectfully submit that one having ordinary skill in the art would recognize that the metes and bounds of claims 1-16 and 37-38 are both clear and definite. Reconsideration and withdrawal of these bases for rejection are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claim 38 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the term “*Escherichia coli* H7:0157” is new matter.

Applicants have amended the term “*Escherichia coli* H7:O157” to recite “*Escherichia coli* O157” thus obviating this basis of rejection. Applicants submit that support for this amendment can be found throughout the specification as filed, for example, on page 20, line 29; thus, no new matter has been added by way of this amendment.

Reconsideration and withdrawal of this basis for rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. § 102(B)

Claims 1-4, 7, 9, 13, and 16 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tuunanen (U.S. Patent No. 6,040,192). Specifically, the Examiner alleges that Tuunanen teaches a method for determining the presence of an analyte in a sample, wherein the method comprises each and every element of claims 1-4, 7, 9, 13, and 16.

Applicants respectfully traverse this basis for rejection and submit that Tuunanen fails to anticipate the presently claimed invention because they do not teach each and every element of the claims. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). M.P.E.P. § 2131.

As an initial note, Applicants, without acquiescence, have amended claims 1 and 3 to recite methods comprising the use of a magnetic unit comprising at least one magnet (13), a ferromagnetic tube (12), and the reactor vessel (26, 61), and wherein conditions in the closed reactor unit (60) are controllable and wherein the at least one magnet (13) and the ferromagnetic tube (12) can be moved in relation to each other in order to adjust the magnetic field strength. Support for this amendment can be found throughout the specification as filed, for example, on page 7, lines 14-24; page 12, lines 6-12; and Figures 1, 3, and 7-9. Thus, no new matter has been added by way of this amendment.

Applicants respectfully submit that Tuunanen does not disclose a device comprising a magnetic unit with a magnet and a ferromagnetic tube, wherein the magnet and the ferromagnetic tube can be moved in relation to each other, *e.g.*, the magnet can be moved in

relation to the tube and the tube can be moved in relation to the magnet, in order to adjust the strength of the magnetic field.

Accordingly, Tuunanen fails to anticipate the presently claimed invention because it does not disclose each and every limitation of the claimed magnetic unit. Reconsideration and withdrawal of this basis for rejection are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)

Claims 1-16, 37, and 38 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Tuunanen in view of Ekenberg (U.S. Patent No. 5,567,326). Specifically, the Examiner alleges that Tuunanen teaches a method for determining the presence of an analyte in a sample, wherein the method comprises each and every element of claims 1-4, 7, 9, 13, and 16.

The Examiner acknowledges that Tuunanen does not expressly disclose the elements of claim 5: a first well comprising channels for rotating the solution comprising the sample in and out of the first well, for adding or removing the sample from the first well, for controlling the gases/liquids added into the first well, for controlling pH value and salt content in the first well, or for filtering the gases/liquid added into the first well. However, the Examiner alleges that MPEP 2144.04, Section III indicates that providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. Therefore, the Examiner concludes that claim 5 is obvious because the inclusion of a channel to send the sample and the diluter into the first well of Tuunanen would have provided automation of the manual activity of introducing the sample and the diluter into the first well.

The Examiner further acknowledges that Tuunanen does not expressly disclose the elements of claims 8 and 12: that the agitation within the first well is by: (1) movement of projections or depressions inside the outer surface of the first well, (2) rotation of the apparatus around its longitudinal axis or by rocking the apparatus, (3) movement of a flexible element in the remover, (4) pushing the bottom of the first well (comprising a stretchy material) downwards, or (5) rotation of the remover (thus rotating the magnets). However, the Examiner alleges that

Tuunanen points out that agitation of the medium can alternatively be promoted by a suitable remover and vessel design (column 2, lines 60-61). Therefore, the Examiner concludes that it would have been obvious to have agitated the contents of the first well by other means, including those means listed above, since there would have been a reasonable expectation of success in agitating the medium by these remover and vessel designs.

In addition, the Examiner acknowledges that Tuunanen does not expressly disclose the elements of claim 6: that the environmental cabinet controls the rotation speeds of the magnets or the gas exchange. However, the Examiner alleges that because it would have been obvious to have rotated the remover (comprising the magnets) to agitate the medium, as discussed above, it follows that it would also have been obvious to have controlled the rotation speed of the remover (and thus the magnets of the remover) in the environmental cabinet since the skilled artisan would have expected that the agitation of the medium is dependent on the rotation speed (the greater the rotation speed, the greater the amount of agitation). Furthermore, the Examiner alleges that it would have been obvious to control the gas exchange at a level that is for optimal durability in the environmental cabinet since Tuunanen indicates that the vessels (the wells) may contain an inert vapor phase to improve durability (column 3, lines 7-8).

The Examiner also acknowledges that Tuunanen does not expressly disclose the limitations of claims 15 and 38: that the analyte being detected (and thus isolated and enriched) is a pathological bacteria, virus, parasite, or protozoa. However, the Examiner alleges that Ekenberg discloses a method for separating target biological substances of interest which involves the separation of magnetic particles from nonmagnetic media, wherein the target substances include cells, cell components, bacteria, parasites, proteins, viruses, specific nucleic acid sequences, DNA, and mRNA. Therefore, the Examiner concludes that it would have been obvious to the person of ordinary skill in the art to have used the device of Tuunanen to separate (thus isolate and enrich) other biological substances, including bacteria, viruses, parasites, other cells such as protozoan cells, cell components, proteins, and specific nucleic acid sequences.

Lastly, the Examiner acknowledges that Tuunanen does not expressly disclose the limitations of claims 14 and 37: performing a step of chromatographic purification of the separated biological components. However, the Examiner concludes it would have been obvious

to have used the separated magnetic particles bound to the biological substances to carry out chromatographic purification (ion exchange, reverse phase, hydrophobic, affinity) since purification by chromatography for detecting and analyzing biological substances is well known within the art, and techniques for performing such were well within the purview of the artisan of ordinary skill.

Applicants respectfully traverse these bases for rejection and submit that the Examiner has failed to establish a *prima facie* case of obviousness against the presently claimed invention. *See In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). As noted above, Applicants have amended claims 1 and 3 to recite methods comprising the use of a magnetic unit comprising at least one magnet (13), a ferromagnetic tube (12), and the reactor vessel (26, 61), and wherein conditions in the closed reactor unit (60) are controllable and wherein the at least one magnet (13) and the ferromagnetic tube (12) can be moved in relation to each other in order to adjust the magnetic field strength.

Obviousness requires a suggestion of all the elements in a claim (*CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)) and an explicit, apparent reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does with a reasonable expectation of success. *See KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007).

Here, the Examiner has not provided any reason, explicit or apparent, that would have prompted a person of ordinary skill in the relevant field to derive a method comprising a magnetic unit comprising at least one magnet (13), a ferromagnetic tube (12), and the reactor vessel (26, 61), wherein the at least one magnet (13) and the ferromagnetic tube (12) can be moved in relation to each other in order to adjust the magnetic field strength.

Therefore, the Examiner's line of reasoning is insufficient to establish a *prima facie* case of obviousness against the claimed invention because the skilled artisan would not have a reasonable expectation of success deriving the claimed method. *See KSR v. Teleflex, Inc.* at 1741, *citing In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”). in the way the claimed new invention does with a reasonable expectation of success

In addition, with regard to the bases of rejection of claims 5, 6, 8, 12, 14, and 37, the Examiner has relied on the knowledge of the skilled artisan to support conclusions of alleged obviousness. Here, the Examiner has not provided any facts to support why the skilled artisan would find the presently claimed methods obvious. Thus, Applicants respectfully submit that the Examiner’s obviousness rationale lacks the requisite factual findings to support a legal conclusion of obviousness. “If a rejection has been made that omits one of the factual findings, and in response to the rejection a practitioner or inventor points out the omission, Office personnel must either withdraw the rejection, or repeat the rejection, including all of the required factual findings.” *Federal Register* Vol. 75, No. 169, Sept. 1, 2010, p. 53645. Applicants submit that the Supreme Court in *KSR*, reiterated that the legal framework for the objective analysis for determining obviousness under 35 U.S.C. 103 are the underlying factual inquiries stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

Thus, for at least these reasons, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness against the presently claimed invention. Reconsideration and withdrawal of these bases for rejection are respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Application No. 10/576,298
Reply to Office Action dated November 9, 2010

All of the claims remaining in the application are now believed to be allowable.
Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,
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